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Re: International Patent Application No. PCT/CH03/000247
"Intervertebral implant"
in the name of Mathys Medizinaltechnik AG
to be transferred to Synthes GmbH

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do hereby certify that I am conversant with the English and German languages, and am a competent translator thereof, and I further certify that to the best of my knowledge and belief the attached document is a true and correct translation made by me of the documents in the German language attached hereto.

Signature of translator: P. Kaiser

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English translation of the International Patent Application No. PCT/CH2003/000247 "Intervertebral implant" in the name of Mathys Medizinaltechnik AG

Intervertebral implant

The invention concerns an intervertebral implant according to the preamble of patent claim 1.

An intervertebral disc prosthesis of the generic type is known from US 4,911,718 Lee. This known intervertebral disc prosthesis comprises a central core, that is so formed from a biocompatible elastomer, that it is almost corresponds to that of the nucleus pulposus of a natural intervertebral disc, as well as from a multi-layer laminate from fibres bound in an elastomer, arranged around the core. Each laminate layer has its own yarn system, so that a plurality of fibre groups are present. The fibres of the individual layers have various orientations, whereby the angles of the fibres relative to the central axis of the intervertebral disc are in the range of ± 20° and ± 50°, preferably 0°, +45° and -45°.

From WO 90/00374 Klaue a hip prosthesis is known, the shaft of which is made from a tubular mesh, i.e. a structure, that comprises at least two series of fibres crossing one another. In this application the interior of the tubular mesh remains empty as the shaft of the femur component.

In the case of the prosthesis disclosed in US 4,911,718 Lee, although the individual fibres are integrated in the laminate that is made from an elastomer or another type of synthetic material, their ends are, however, adhered only to the end plates, so that they do not surround the core and consequently, in the case of a radial expansion of the core, cannot accept any tensile force. When adhering the lateral walls, cut out from the fibrous matrix compound, to the end plate, a fixing of the integrated fibres on the end plate is quite difficult, only the cross-section of the fibre offers a contact surface for the chemical joint. Therefore increased stresses occur especially on these joining places of the fibres on the end plate.

Furthermore, in the case of Lee the length of the individual fibres is only from the bottom cover plate to the top cover plate, what corresponds to the sheathing height or a diagonal of the projected sheathing height. Thus the forces occurring can be reduced only along these lengths due to the transfer of the shearing force of the fibres to the elastomer. Thus positions of increased stresses result at the fixings, i.e. on the ends of the fibres.

The prosthesis disclosed in WO 90/00374 Klaue comprises a system of fibres, the individual fibres of which are not fixed on both ends, as well as there is no deformable core. Therefore in the case of an axial compression of the prosthesis the axial compression forces occurring cannot be transferred as tensile forces to the fibres.

From US-A 3,867,728 Stubstad et al. an intervertebral disc prosthesis is known, that has an elastomeric sandwich structure with a fibre system. A disadvantage of this known prosthesis is that the fibre system, joined with the cover plates, is either not embedded in the sheathing body or in another embodiment is embedded in a multi-layer laminate of an elastomer.

This is where the invention wants to provide remedy. The object of the invention is to produce an intervertebral implant, that comprises a fibre system joined with the cover plates, by virtue of which a sheathing body, surrounding the central part and made from a homogeneous material, will be reinforced.

The inventions achieves this objective with an intervertebral implant having the features of claim 1.

The basic advantages, achieved by the invention, are that with the intervertebral implant according to the invention

- the fibre system can be first wound around the central part and following this poured into an elastomer forming the elastic sheathing body, so that the sheathing, enveloping the central part, can be easily produced,

- by applying the elastic material around the fibre system after its winding, the anchoring of the fibre system is possible by various means, for example also on the opposing inner surfaces of the cover plates,
- the central part allows a movement of both adjacent bodies of the vertebra in the case of a compression, flexion or extension, lateral bending and torsion,

- the momentary centre of rotation or the momentary axes of rotation are not determined by the intervertebral implant itself, and they can position themselves according to the rule of minimum forces or moments occurring,

- by varying the number of fibres in the circumferential direction, the cross-section of the fibres and the choice of material, the behaviour of the intervertebral implant can be so adjusted, that under varying loads the movements occur as in the case of the natural intervertebral disc, and

- by varying the arrangement and the execution of the fibre system certain movement limitations can be placed on the intervertebral implant, and from a certain deformation a limit region occurs, where despite the further increasing forces no deformation takes place or in the case of moments occurring the implant will no longer tilt.

The axial compression forces occurring under a load on the spinal column are transmitted to the central part via the two end plates. The compression forces deform the central part situated between the two end plates, in particular an elastic formed body situated therein, in such a manner that the central part radially buckles. This expansion of the central part is restricted by the fibre system surrounding the central part and the radial compression forces arising can be absorbed by the fibre system as a tensile force. Thus a further, disadvantageous buckling of the central part can be

limited. By anchoring the fibre system in both cover plates, the intervertebral implant remains stable even under the greatest loads and the fibre system is capable to withstand even considerable tensile forces.

In a preferred embodiment the entire fibre system is embedded in the elastic sheathing body, so that the fibre system does not necessarily need to be made from a biocompatible material.

In a further embodiment the fibre system is only partially embedded in the elastic sheathing body, while the fibre system has a radial thickness δ relative to the central axis and the elastic sheathing body has a radial thickness d, and the $\delta/d \times 100\%$ ratio is in a range of 80% and 350%. By virtue of this the advantages can be achieved, that the large relative movements in the peripheral region of the cover plates occurring during a flexion/extension movement or a lateral movement of the adjacent bodies of the vertebra are not subjected to a great resistance by the elastic sheathing body and due to this the danger of a fissure formation in the sheathing body is slighter.

The embedding of the fibre system in the elastic sheathing body can be carried out various embodiments in such a manner, that

a) the fibre system can be moved relative to the elastic material of the sheathing body,

or

b) the fibre system cannot be moved relative to the elastic material of the sheathing body.

In yet another embodiment the entire fibre system is anchored on the cover plates, so that greater tensile forces can be accepted by the fibre system, and consequently the intervertebral implant obtains a great torsional rigidity.

In another embodiment the sheathing body, accommodating the fibre system, is made from an elastic, biocompatible material, preferably an elastomer, produced in particular based on polyurethane (PUR). However, silicone rubber, polyethylene, polycarbonate urethane (PCU) or polyethylene terephthalate (PET) may also be used.

In yet another embodiment the central part is filled at least partially with an incompressible medium, preferably a liquid.

In another embodiment the central part comprises an incompressible liquid core and an elastic formed body provided around it, while the liquid can be accommodated, for example, in a cavity provided in the formed body. This brings with it the advantage, that by virtue of the liquid core a mechanical behaviour of the intervertebral implant is similar to that of a physiological intervertebral disc. The axial deformation of the elastic central part will result in the radial expansion of the incompressible liquid and consequently in the radial expansion of the wall of the central part containing the fibre system. The tensile forces, occurring due to the radial expansion and/or the buckling of the wall of the central part, are basically absorbed by the fibres.

The anchoring of the fibres on the cover plates can be carried out, for example, in the following manner:

a) Mechanically by guiding the endless fibres through grooves and over the external surfaces of the cover plates from one groove to another one. Thus the fibres surround the central part together with the cover plates. By guiding the fibres in the grooves the fibre system can be so anchored on the cover plates, that in the case of tensile forces acting on the fibres no slipping of the fibres on the lateral sides is possible because the fibres can absorb only tensile forces,

b) Mechanically by a wedge-shaped construction of the grooves, so that the fibres extending from cover plate to cover plate can be firmly clamped in the grooves,

and/or

c) By adhering the fibre system on the cover plates.

In yet another embodiment of the intervertebral implant according to the invention each cover plate comprises on its periphery a lateral surface and grooves distributed on the circumference and radially penetrating into the lateral surfaces. The fibres, part of this fibre system, are guided through these grooves.

In a further embodiment the central part and the fibre system are joined with the cover plates in a form-locking manner.

In yet a further embodiment the fibre system is guided over the external surfaces of both cover plates, so that it will surround the central part as well as the cover plates.

When using an endless fibre, that covers the entire implant, the stresses preferably are distributed on the entire circumference of this winding. The fibre system is preferably in the form of a woven material, fabric or is knitted.

In another embodiment channels are mortised in the external surfaces of the cover plates to accommodate the fibre system.

In yet another embodiment the central part is essentially hollow-cylindrical, hollow-prismatic or is a body of rotation, an ellipsoid, a partial sphere or barrel-shaped with an axis of rotation that is coaxial with the central axis. By virtue of such configurations the advantage, that the positions of the axes of rotation of the adjacent intervertebral discs correspond, as far as possible, to that of the natural intervertebral disc, can be achieved.

The fibre system can be made, for example, from UHMWPE (ultra high molecular weight polyethylene) or from PET (polyethylene terephthalate).

In a further embodiment of the intervertebral implant according to the invention a closing plate is fastened on each cover plate for placing the adjacent bodies of the vertebra on the base plate or cover plate, each of the said closing plate having an external surface at right angles to the central axis with a macroscopic structure. The structure may be, for example, in the form of teeth. The macroscopic structure allows a primary stabilisation of the intervertebral implant immediately after the operation. Thus a mechanical anchoring of the intervertebral implant at a time when the growing of the bone on the intervertebral implant has not yet taken place, can be achieved.

In yet a further embodiment the woven material is formed from first and second fibres, wherein the first fibres include an angle α with the central axis and the second fibres include an angle β with the central axis. The angles for α or β are preferably between 15° and 60°.

In another embodiment the first and second fibres are interwoven with one another.

In yet another embodiment the elastic formed body has at right angles to the central axis a cross-sectional surface F_F, while the central part has at right angles to the central axis a cross-sectional surface F_M and the F_F/F_M ratio of these two cross-sectional surfaces is between 30% and 65%.

In a further embodiment the elastic formed body is surrounded by a semi-permeable membrane, while in the interior of the elastic formed body preferably physiological table salt solution is present.

With regard to the central axis the fibre system may be single-layered or multi-layered, preferably 2-6 layered. Furthermore, the fibre system can be wound on the elastic formed body. The winding on the elastic formed body can be in two different directions, preferably rotationally symmetrically.

In yet another further embodiment a closing plate can be fastened on each cover plate, the closing plate having at right angles to the central axis an external surface with a macroscopic structure, preferably in the form of teeth.

The diameter of the fibres is in a range of 0.005 mm and 0.025 mm. A yarn (roving) is preferably produced from a plurality of fibres, whereby 500-2000 fibres form a yarn with a cross-sectional surface of 0.5 mm^2 to 2 mm^2.

In those embodiments, wherein the fibre system has fibre sections crossing one another, in the case of flexion movements (flexion, extension, lateral flexion) of the patients some fibre sections will be unilaterally clamped and in case of shearing the fibre sections extending tangentially to the shearing direction absorb the forces.

The invention and developments of the invention are explained in detail in the following based on partially schematic illustrations of several embodiments. They show in:

Fig.1 - a side view of an embodiment of the intervertebral implant according to the invention,

Fig.2 - a top view on the embodiment of the intervertebral implant according to the invention, illustrated in Fig.1,

Fig.3 - a side view of another embodiment of the intervertebral implant according to the invention,

Fig.4 - a section through the embodiment of the intervertebral implant according to the invention, illustrated in Fig.3,

Fig.5a - a perspective illustration of the fibre system of an embodiment of the intervertebral implant according to the invention,

Fig.5b - a top view on the fibre system illustrated in Fig.5a,

Fig.6a - a perspective illustration of the fibre system of an embodiment of the intervertebral implant according to the invention,

Fig.6b - a top view on the fibre system illustrated in Fig.6a, and

Fig.7 - a section through a further embodiment of the intervertebral implant according to the invention.

Figs.1 and 2 illustrate an embodiment of the intervertebral implant 1 according to the invention, that comprises a top cover plate 3 and a bottom cover plate 4, each with an external surface 7, 8 extending at right angles to the central axis 2 and having a lateral surface 21, 22 on the periphery. Between the cover plates 3, 4 there is a central part 10 provided with a central cavity 11 and a sheathing 12, that surrounds the fibre system 5. For the purpose of anchoring the fibres 6 of the fibre system 5 on the cover plates 3, 4, each of the peripheral lateral surfaces 21, 22 has grooves 18, distributed on the circumference and radially protruding into the lateral surfaces 21, 22, so that the fibre system 5 can be anchored in these grooves 18. In the central cavity 11 there is an elastically deformable formed body 9 with an incompressible core, preferably a liquid core 13. Due to the incompressibility of the liquid core 13 during a compression of the cover plates 3, 4 parallel to the longitudinal axis 2, for example, the elastic formed body 9 and the sheathing 12 with the fibre system 5 will buckle radially, i.e. at right angles to the longitudinal axis 2, consequently the fibres 6 will be under tension.

Figs.3 and 4 illustrate an embodiment of the intervertebral implant 1 according to the invention, that comprises two cover plates 3, 4, provided at right angles to the central axis 2, and an elastically deformable central part 10 situated between them. The central part 10 comprises a hollow-cylindrical sheathing 12 that is coaxial with the central axis 2 and a central cavity 11. In the central cavity 11 an elastic formed body 9 with an incompressible core is provided, preferably a liquid core 13. The formed body 9 is surrounded by a semi-permeable membrane, whereas the sheathing 12, that

surrounds the fibre system 5 and an elastic sheathing body 25 passed through by the fibre system 5, is made from a synthetic material. The closing plates 14, 15 are firmly joined with the cover plates 3, 4 and have axially protruding surfaces 16, 17, which can be brought to rest on the end plates of two adjacent bodies of the vertebra. The fibre system 5 is anchored on the cover plates 3, 4 and is integrated in the sheathing 12 and its purpose is to absorb the forces on the central part 10, said forces acting on the intervertebral implant 1 via the bodies of the vertebra adjacent to the closing plates 14, 15, i.e. torsional forces due to the rotation of the bodies of the vertebra about the central axis 2 relative to one another or bending moments due to lateral bending and/or flexion/extension of the spinal column. For example, a compression force, acting on the intervertebral implant 1 parallel to the central axis 2, is transferred by both closing plates 14, 15 via both cover plates 3,4 to the central part 10, while as the result the elastic formed body 9 will buckle at right angles to the central axis 2. This expansion movement of the elastic formed body 9 is transferred to the sheathing 12 with the fibre system 5 and contained by this. Since the fibre system 5 is anchored on the cover plates 3, 4, the compression force, acting transversely to the central axis 2, generates tensile forces in the fibres of the fibre system 5. The fibre system 5 in this case is made from synthetic fibres, preferably from UHMWPE-fibres (ultra high molecular weight polyethylene) or from PET (polyethylene terephthalate) and comprises a mesh from first and second fibres 6a, 6b, that are interwoven with one another. By doing so, the first fibres 6a include an angle α and the second fibres 6b an angle β with the central axis 2. In the embodiment of the intervertebral implant 1 according to the invention illustrated here, the angles α and β are equal and are between 15° and 60°. The fibres 6a, 6b are anchored on the cover plates 3, 4 by means of grooves 18 that are arranged on the circumference of the cover plates 3, 4 parallel to the central axis 2, so that the fibres 6a, 6b are passed through the grooves 18 and can be guided to the next groove 18 over the surfaces 7, 8 in a channel 19. The cover plates 3, 4 are made from synthetic material, whereas the closing plates 14, 15, arranged externally, are made from titanium or a titanium alloy. The externally arranged closing plates 14, 15 are joined with the cover plates 3, 4 either by form-locking or frictional locking. In particular they can be adhered or welded to one another.

In Figs.5a and 5b a fibre system 5 is illustrated according to an embodiment of the intervertebral implant 1 according to the invention, wherein the fibres 6 extending over the end plates 3, 4 form chords on the circular surfaces 7, 8 of the cover plates 3, 4.

In Figs.6a and 6b a fibre system 5 is illustrated according to an embodiment of the intervertebral implant 1 according to the invention, wherein the fibres 6 extending over the end plates 3, 4 cross at the point of intersection of the central axis 2 and the end plates 3, 4.

When compared with the arrangement of the fibres 6 (Figs.6a, 6b), the guiding of the fibres 6 as chords (Figs.5a, 5b) over the surfaces 7, 8 of the end plates 3, 4 has the following advantages:

- due to the better distribution of the crossing points of the fibres 6 no concentration will occur, especially between the external surfaces 7, 8 of the cover plates 3, 4 and the closing plates 14, 15 (Figs.3 and 4), and

- with the aid of a winding technique the fibre system 5 can be symmetrically produced relative the central axis 2 while the intervertebral implant 1 can be clamped in at the points of intersection between the central axis 2 and the cover plates 3, 4.

Fig.7 illustrates an embodiment, that differs from the embodiment illustrated in Figs.3 and 4 only by that the periphery of the sheathing 12 provided on the central part 10 comprises an elastic sheathing body 25 only partially passed through by the fibre system 5, the thickness of the sheathing body *d* being smaller than the radial thickness δ of the fibre system.